EFFICACY REVIEW

PRODUCT: d-CON Bait Station XII

REG. NUMBER: 3282-RNG

DATE: August 26, 2010

DP BARCODE: 375495

DECISION: 428330

GLP: Yes

CHEMICAL: Diphacinone (0.005%)

CHEMICAL NUMBER: 067701

PURPOSE: Review data to determine if it supports the claim for a Tier I bait station.

MRID: **47981601**. Ward, Richard A. (2009). Evaluation of the Tethys Refillable Mouse Bait Station for Adult Opening, Refilling, and Reclosing Test for Reckitt Benckiser. Submitted by Reckitt Benckiser.
47981602. Ward, Richard A. (2009) Evaluation of the Tethys Refillable Mouse Bait Station for Unsecured Tamper-Resistant Test for Reckitt Benckiser. Submitted by Reckitt Benckiser.
47981603 Watson, Duncan. (2010). Weather Resistance of d-CON Bait Station XII. Submitted by Reckitt Benckiser.
47981604 Dixon, Lori Mitchell, PhD. (2009). The Evaluation of d-CON Bait Station XII Tamper Resistant to Dogs. Submitted by Reckitt Benckiser.

TEAM REVIEWER: Jennifer Gaines

EFFICACY REVIEWER: Jennifer Gaines, Wildlife Biologist Jennifer Gaines

SECONDARY EFFICACY REVIEWER: John Hebert, PM 07, Insecticide-Rodenticide Branch

BACKGROUND:

On May 28, 2008, the Agency published the Risk Mitigation Decision for Ten Rodenticides with the intent of minimizing children's exposure to rodenticides used in homes and to reduce wildlife exposures and ecological risks. In order to achieve this goal of reduced child exposure, all bait products marketed to general and residential consumers must be sold only with bait stations. The Agency identified four different tiers of bait stations based on the level of tamper resistance which are: **Tier IV** - Not tamper-resistant; **Tier III** – Tamper-

resistant to young children only; **Tier II** – Tamper-resistant to dogs and young children (but not weather resistant); and **Tier I** – Weather-resistant and tamper-resistant to children and dogs.

The following criteria determine what tier level the bait station will receive:

- Tier IV: The bait station is either untested or it is tested but does not meet and of the tamper-resistance criteria.
- Tier III: **(Non-refillable stations)** The submitted study must result in 85% child-resistant effectiveness; **(Refillable stations)** The submitted study must result in 90% child-resistant effectiveness or greater before the demonstration and 85% or greater for the entire 10-minute testing period.
- Tier II: In addition to meeting the above requirement for Tier III status, the dog test results must indicate the station completely denies access or potential access to the bait for 100% of the test subjects with no failures accepted.
- Tier I: Justification for weather-resistance in addition to meeting Tier II and Tier III status.

The Agency received an application from the registrant Reckitt Benckiser to register d-CON Bait Station XIV (the Station), a Tier I non-refillable bait station containing 0.005% of the first generation anticoagulant diphacinone. Due to its Tier I status, this product is labeled for use to control only house mice inside and outside (within 50 feet) of homes in areas accessible to children and pets. In accordance with the 1998 RMD, the label states "*This Bait Station is Resistant to Weather and to Tampering by Children and Dogs. For Use Indoors and Outdoors.*"

The registrant submitted the following studies for review to support the tier I status of d-CON Bait Station XIV. Additionally, it should be noted that the submitted study tested a refillable bait station, d-CON Bait Station XII, while the proposed product is a non-refillable bait station, d-CON Bait Station XIV. Given that a refillable bait station can pose a greater risk of exposure to the user than a non-refillable station, the submitted studies can be used to support the registration of d-CON Bait Station XIV.

DATA REVIEW:

The efficacy reports for review are cited and discussed below:

Ward, Richard A. (2009) Evaluation of Tethys Refillable Mouse Station for Adult Opening, Refilling, and Reclosing Test for Reckitt Benckiser. EPA/OPP Designation 1.228 Study No. 1207-094, Perritt Laboratories, Inc., Highstown, NJ 21 pp. MRID # 47981601.

Ward, Richard A. (2009) Evaluation of the Tethys Refillable Mouse Bait Station for Unsecured Tamper-Resistant Test for Reckitt Benckiser. EPA/OPP Designation 1.229 Study No. 1207-093, Perritt Laboratories, Inc., Highstown, NJ 19 pp. MRID # 47981602.

Watson, Duncan. (2010) Weather Resistance of d-CON Bait Station XII. Reckitt Benckiser Inc., Morris Corporate Center IV, 399 Interpace Parkway, Parsippany, NJ 5 pp. MRID # 47981603.

Dixon, Lori Mitchell, PhD., The Evaluation of d-CON Bait Station XII Tamper Resistant to Dogs. EPA/OPP Designation 1.230, Great Lakes Marketing, 3103 Executive Pkwy, Ste. 106, Toledo, OH 71 pp. MRID # 47981604.

A. Adult Test

Ward, Richard A. (2009) Evaluation of Tethys Refillable Mouse Station for Adult Opening, Refilling, and Reclosing Test for Reckitt Benckiser.

Since this test assessed whether the bait station can be properly opened and closed (refillable), this test is not relevant and will not have an effect on the tier I determination of the product in question.

B. Tamper-Resistant Test (Children)

Ward, Richard A. (2009) Evaluation of the Tethys Refillable Mouse Bait Station for Unsecured Tamper-Resistant Test for Reckitt Benckiser.

Protocol 1.229 was designed with the purpose of testing the abilities of ready-to-use bait stations to isolate bait from children of pre-school age and includes test methods that can be used to test secured and unsecured bait stations. The protocol specifies the use of 200 healthy children, aged 42-51 months of age, inclusive, for testing of both secured and unsecured bait stations. The registrant does have the option to do sequential testing of groups of 50 children as an alternative to the 200-child test.

This study tested 50 children between the ages of 42 and 51 months distributed into three age groups, 42-44 months; 45-48 months; and 49-51 months evenly distributed by sex. Each bait station tested included a placebo wax block with indicator on all surfaces except that which was visible in the window. The indicator used was red lipstick. The children in the age range of 42-44 months consisted of 7 males and 8 females; the 45-48 month age range consisted of 10 males and 10 females; and the 49-51 month age range consisted of 8 males and 7 females.

The test was administered for ten minutes, which conforms to the timeframe indicated in Protocol 1.229. After the first five minutes, the interviewer stopped the test and reminded the children that they may use their teeth and feet per Protocol procedures. The test was then continued for the remaining five minutes in which the results were recorded.

Of the 50 children tested, there were zero failures. No children were successful in gaining access to or touching the indicator on the placebo in the first five minutes and no children were successful in gaining access to or touching the indicator on the placebo in the second five minutes.

Additionally, it should be noted that the submitted study tested a refillable bait station while the proposed registration's product is a non-refillable bait station. Since a refillable bait station can pose a greater risk of exposure to the user and the test results indicated the bait station passed, this test can be used to support the registration of d-CON Bait Station XIV.

C. Weather Resistance

Watson, Duncan. (2010) Weather Resistance of d-CON Bait Station XII.

The Agency does not require a specific study to determine the weatherability of a bait station, however, the registrant must provide justification for deeming the bait station "weather resistant". Therefore, the registrant submitted a detailed description of the bait station explaining the design features and construction materials that make it weather resistant.

The bait station is made of the hydrophobic material polypropylene which generally results in the repelling and beading of rainwater droplets instead of it spreading along the surface and seeping into the material. The station's hydrophobic property will also help prevent damage caused by humidity and other

sources of water and moisture. The bait station also contains a "6 mm high bund wall" surrounding the bait in addition to a bait platform that is 6 mm above ground level. This "bund wall" is used to prevent water from contacting the bait which the bait platform further places the bait out of the reach of water. Additionally, the entry ridge to gain access to the station is 4 mm high, which will aid in the drainage of rainwater from the station before it comes into contact with the bait.

The bait station contains the following additional features to support its weather resistance claim: A transparent window to protect the bait from direct rain impact, central location of the bait, four drainage holes, and splash walls to minimize rain splashing directly onto the bait. Furthermore, the bait station contains a UV stabilizer which prevents or slows degradation caused by ultraviolet radiation exposure. Even after treatment with a UV stabilizer, the product can still decay, but this will occur at a much slower pace than if there were no stabilized added.

With melting and heat deflection temperatures of 267° C and 145° C for polycarbonate, respectively, the expected temperature range of -10° C to 50° C the bait station will be exposed to is well within polycarbonate's tolerance range.[1] Polypropylene has a deflection temperature ranging from 70° C to 100° C with a melting point of 160° C indicating this substance would also be able to withstand exposure the expected temperature range of -10° C to 50° C.[2] Based on this information, minimal, if any alteration of their properties would occur. Therefore, the bait station should not suffer structural damage.

D. <u>Tamper Resistance to Dogs</u>

Dixon, Lori Mitchell, PhD., The Evaluation of d-CON® Bait Station XII Tamper Resistant to Dogs.

The registrant also submitted a study testing the ability of the bait station to isolate the bait from dogs in accordance with OPP Protocol 1.230 to support the claim of the station being tamper resistant to dogs. The protocol requires the use of at least 6 adults dogs weighing at least 60 pounds each. The dogs must be healthy, not excessively fat, and between 1-6 years old. Each group of six dogs must include at least 2 females and 2 males with any type of breeds including mixed-breeds. Each test subject can be used only once with a specific bait station design. The same subject can not be used to test more than two bait station designs.

The study was performed on one group of six dogs using unsecured stations only; secured stations were not used, therefore a second group of six dogs were not tested. In an e-mail correspondence on August 16, 2010 with Dr. Lori Dixon of Great Lakes Marketing, she explained the reason for this is because the bait station lacked a means to attach it to a substrate.

A total of 6 dogs (3 males and 3 females) were used for this test with half of the test sites at the dog's home and the other half at a kennel. In accordance with the Protocol, dogs were conditioned to be fed once a day at the same time every day, all food sources were removed from the dog after a maximum of 60 minutes following meal time the day before testing, with the test taking place the following day at the normal feeding time and lasting for two hours at a time. See Table I.

1. http://en.wikipedia.org/wiki/Polycarbonate
2. http://www.matweb.com/reference/deflection-temperature.aspx

All interactions with the station were observed and recorded by the test administrator. When given the bait station, the initial reaction (within the first 5 seconds) from three of the six subjects was to sniff it; this was

displayed among dogs 4T, 6T, and 10T with dog 12T licking, pawing, and picking the station up in its mouth in addition to sniffing. Dog 2T licked the station while dogs 8T had no contact with the station during this time. There was minimum contact with the stations by the test subjects throughout the duration of the study as noted in Table II. However, dog 12T had the most contact by picking the station up in its mouth and chewed the station while holding it in its paws. This progressed for 71 seconds.

Table I.

Dog/Station No.	Name of Dog	Age	Gender	Breed	Test Site	Normal Feed Time	Testing Start Time	Testing End Time
2T	Ezzy	1-2 y/o	Female	G. Sheppard	Home	7:30 a.m.	7:35 a.m.	9:35 a.m.
4T	Bubbles	3-4 y/o	Female	English Bulldog	Home	7:30 a.m. – 9:30 a.m.	7:30 a.m.	9:30 a.m.
6T	Ace	1-2 y/o	Male	English Bulldog	Kennel	7:30 – 9:30 a.m.	7:30 a.m.	9:30 a.m.
8T	Ned	5-6 y/o	Male	Mixed	Kennel	8:00 a.m.	8:20 a.m.	10:20 a.m.
10T	Brisco	5-6 y/o	Male	Yellow Lab	Home	7:00 a.m.	7:00 a.m.	9:00 a.m.
12T	Satchel	1-2 y/o	Female	Australian Shepherd	Home	3:00 p.m.	3:00 p.m.	5:00 p.m.

Table II.

Dog/Station No.	Initial Reaction at Placement (1-5 sec.)	Attempts After Initial Reaction at Placement of Station					Pass/Fail
		Sniffs (1-5 sec.)	Licks (1-5 sec.)	Pawed (1-5 sec.)	In Mouth (1-5 sec.)	Contact longer than 5 sec.	
2T	Licked	1	1	2	2	None	Pass
4T	Sniffed	2	0	0	0	Sniffed and pushed with nose for 13 sec.	Pass
6T	Sniffed	4	0	6	0	None	Pass
8T	No Contact	1	0	4	7	None	Pass
10T	Sniffed	0	0	0	0	None	Pass
12T	Sniffed, Licked, Pawed, Picked up in Mouth	0	1	0	5	Sniffed and nudged for 5-10 sec.	Pass

Conclusions:

A. Adult Test

The result of the adult study (MRID # 47981601) tested their ability to properly use Reckitt Benckiser's product, d-CON XII, a refillable bait station. The methods followed were consistent with those listed in Protocol 1.228 for a refillable bait station, but not for a disposable bait station. The Protocol contains two sections that detail test procedures specific to the type of bait station (refillable or non-refillable). Section 4 is for non-refillable bait stations; while section 5 is for refillable bait stations. Furthermore, the focus of the procedures listed in Section 4 is whether the test subject can successfully secure the station. In addition to the tested bait station being refillable, it is not meant to be secured so it lacks the mechanisms required to be

secured. These factors result in this test as non-relevant to this product. However, the results of the study indicate the bait station passes the requirements necessary for its use as a refillable bait station.

B. Tamper-Resistant Test (Children)

The results of the child-resistant test (MRID #47981602) indicate there were zero failures. Although the station used for the study was a refillable model, these results can be used to support registration of d-CON XIV since refillable stations pose a greater risk of exposure than non-refillable stations. Protocol 1.229 requires sequential testing of 50 children if this method is used as an alternative to using 200 children. While this study used 50 children, they did not perform it sequentially. However, the success of the station at preventing children access to the bait was demonstrated. If future studies involve using 50 children, they must be performed sequentially.

C. Weather Resistance

The justification provided by the registrant is sufficient in supporting the weather resistance claim of this product.

D. Tamper Resistance to Dogs

A revised dog protocol was signed on May 19, 2009 which Reckitt Benckiser was not made aware of. As a result, the submitted dog study (MRID #47981604) follows Protocol 1.230 in its original form. Reckitt Benckiser will be advised of this change and required to submit any future dog studies based on the revised protocol. This review pertains only to MRID #47981604 and the pending product d-CON XIV. Should the registrant decide to submit additional applications for Tier I bait stations, they must perform the dog test following the revised May 19, 2009 dog protocol.

As such, the results of the submitted study indicate there were no failures. None of the dogs were able to gain access to the bait contained in the bait station. This study may be used to support a Tier I status for d-CON XIV.

The submitted studies support the use of d-CON XIV as a tier I bait station.